510(k) Summary
per 21 CFR §807.92

OCT 26 2012

Sponsor:	Boston Scientific Corporation One Boston Scientific Place Natick MA 01760
Contact Person:	Rachel Owens
Phone Number:	763-494-1491
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Prepared:	27 September 2012
Trade Name:	Torque Device
Common Name:	wire, guide, catheter
Classification:	II
Product Code:	DQX 21 CFR 870.1330
Predicate Device:	SCIMED® Sideliner™ Torque Device (K922706; 10 December 1992) Encore 26 Advantage Kit (K120694, 03 April 2012).

Device Description:

The Torque Device is an accessory device used to apply torsional and/or axial force to the guidewire to manipulate its distal end in the vasculature. It is designed to accommodate guidewires with diameters from 0.010 to 0.018 inches and is composed of three main components: 1.) a tubular collet contained within the body and cap assembly; 2.) a cap and 3.) a tubular body.

A guidewire is inserted through the Torque Device from the distal (cap) end. The Torque Device is positioned optimally on the guidewire at the desired location, and then secured by rotation of the cap. Once tightened, the torque device is used to apply torsional and axial force to the guidewire to manipulate its distal end in the vasculature.

Intended Use

The Torque Device is used for guidewire manipulation during general intravascular procedures.

Substantial Equivalence

The Torque Device design, materials, manufacturing process and intended use are substantially equivalent to the Sideliner Torque Device (K922706) and Encore 26 Advantage Kit (K120694).

Summary of Non-Clinical Testing

Design verification was performed to verify the performance and usability of the Torque Device remains substantially equivalent to the predicate device. Biocompatibility and sterility testing were also performed to verify the overall substantial equivalence to the predicates.

Specifically the following design verification testing was performed:

- Torque Slip Force
- Pull Slip Force
- Guidewire Deformation
- Collet Release
- Biocompatibility Testing: Latex

Summary of Clinical Testing

Clinical Evaluation was not required for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
White Oak Building 66
Silver Spring, MD 20993

OCT 2 6 2012

Boston Scientific Corporation
c/o Rachel Owens
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

Re: K123024
Trade Name: Torque Device
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: September 27, 2012
Received: September 28, 2012

Dear Ms. Owens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devises
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Torque Device

Indications For Use:

The Torque Device is used for guidewire manipulation during general intravascular procedures.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K123027